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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,020	06/28/2005	Kenji Fujii	Q88147	4034

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
08/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/541,020	**Applicant(s)** FUJII ET AL.	
	Examiner LESLIE A. ROYDS	**Art Unit** 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 August 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *28-30,37 and 38*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
    See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

Continuation of 5. Applicant's reply has overcome the following rejection(s): the obviousness-type double patenting rejection of claims 28, 30 and 32-33 over claims 6 and 10-19 of US Application No. 11/596,059.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant traverses the instant rejection under 103(a), stating that there is physiological fatigue, which manifests in a healthy individual, and pathological fatigue, which manifests in patients with a physical disorder. Applicant submits that the object of the instant invention is the reduction of physiological fatigue rather than reduction of extreme fatigue due to disease as taught by Fujii et al. Applicant alleges that the reference to Fujii et al. does not teach the instant objective of reducing physiological fatigue as instantly claimed. Applicant also relies upon Examples 1-4 of the instant specification in support of the allegedly "unexpectedly remarkable effect" of the instantly claimed combination therapy for treating fatigue.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Though Applicant argues that the instant claims treat "physiological fatigue" and not "pathological fatigue" such as that which would result from a disease, the instant claims are still not so limited in this regard. The claims circumscribe the treatment of animals in a state of fatigue wherein the fatigue is physical exhaustion caused by exercise or fatigue that is caused by aging, but fails to specify that the fatigued animal is healthy and free from disease (i.e., "physiological fatigue" as described by Applicant). In other words, Applicant is arguing that the claimed invention is directed to the treatment of fatigue resulting from physical exhaustion caused by exercise in healthy individuals and not in individuals that suffer physical exhaustion caused by exercise wherein a concomitant disease may be present that contributes to said fatigue, but the claims fail to recite any limitations directed to the treatment of animals or patients that are otherwise "healthy". Thus, in response to Applicant's argument that the references fail to show this feature of Applicant's invention, i.e., specifically, that the animal is healthy and suffers from "physiological fatigue", not fatigue that may result from disease, it is noted that this feature upon which Applicant relies is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed.Cir. 1993).

Furthermore, the reliance on Examples 1-4 is also unpersuasive in establishing error. With regard to Example 1, please note that the total concentration of coenzyme Q that appears in the muscle using reduced CoQ10 versus oxidized CoQ10 versus the control all fall within the standard deviation of one another and, thus, do not demonstrate any unexpectedly greater effect using "reduced coenzyme Q10" versus "oxidized CoQ10". With regard to Example 2, while reduced coenzyme Q10 demonstrated a greater concentration in the muscle versus the control or oxidized CoQ10, this would have been reasonably expected because reduced coenzyme Q10 was the agent actually being administered and, thus, would have been expected to result in a greater concentration in the muscle. With regard to Example 3, while it has been demonstrated that the reduced coenzyme Q10 or oxidized coenzyme Q10 prolonged maximum running time via reducing fatigue, it is noted that (1) the tested rats were "young rats" and not "middle aged or older rats" as instantly claimed, (2) the combination of reduced and oxidized CoQ10 (to which some of the instant claims are directed) was never tested, and (3) only a single dosage amount of each was tested (i.e., 300 mg/kg), to which the claims are not limited. Accordingly, these results are not probative of nonobviousness of the full scope of subject matter presently claimed. Lastly, with regard to Example 4, it is noted that (1) the combination of reduced and oxidized CoQ10 (to which some of the instant claims are directed) was never tested, and (2) only a single dosage amount of each was tested (i.e., 300 mg/kg), to which the claims are not limited. Accordingly, these results are also not probative of nonobviousness of the full scope of subject matter presently claimed.

For these reasons, the remarks are unpersuasive and the rejection stands for the reasons of record set forth in the final rejection of May 18, 2009

/Leslie A. Royds/
Patent Examiner, Art Unit 1614 .